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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/645,652

08/20/2003

Wendy Naimark

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7590

06/17/2008

JONES DAY  
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EXAMINER

WITCZAK, CATHERINE

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

06/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/645,652	<b>Applicant(s)</b> NAIMARK ET AL.	
	<b>Examiner</b> CATHERINE N. WITCZAK	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 6, 7, 16 and 20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29-31 and 33 is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-15, 17-19, 21-28 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 3, 5, 8, 10, 11, 12, 15, 17, 18, 19, 22, 23, 24, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Barath et al (US 5,112,305).

Barath discloses in Figure 1 a catheter having a balloon (1), a plurality of rupturable micro-needles (10; column 3, lines 16-40), an interior compartment (Figure 5) for containing active material, a catheter lumen used for both inflating the balloon and delivering the active material, and the length of the microneedles being 0.25mm.

2. Claims 1, 2, 4, 5, 15, 17, 18, 19, 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Vigil et al (US 5,713,863).

Vigil et al disclose in Figure 6 a catheter (20), a balloon (30), a plurality of rupturable micro-needles (40) disposed on a plate (Figures 5B and 6B), an interior compartment (38) for containing active material, and a first lumen (38) used to deliver an active material and a second lumen for inflating the balloon.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 9-13, 14, 21-24, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barath OR Vigil et al in view of Yuzhakov et al (US 6,565,532).

Barath OR Vigil et al disclose the claimed invention except for there being between 10 and 1,000,000 microneedles per cm<sup>2</sup> on the outer surface of the balloon, with the diameter of the microneedles being between 10nm and 1mm. Yuzhakov et al teach in column 6, lines 41-58 that it is known to use microneedles with a diameter between 10nm and 1mm in a density of 10 and 1,000,000 microneedles per cm<sup>2</sup>. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Barath OR Vigil et al with microneedles having a diameter and density as taught by Yuzhakov, since such a modification would provide the system with more effective microneedle penetration.

***Allowable Subject Matter***

4. Claims 29-30 and 33 are allowed.

5. Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

Applicant's arguments filed 5/21/2008 have been fully considered but they are not persuasive. Applicants argue that neither Barath nor Vigil disclose devices comprising microneedles. Examiner disagrees. While neither Barath nor Vigil expressly refer to their devices as microneedles, their use (being inserted into the vasculature to puncture a vessel) make it clear to one having ordinary skill in the art that the size of these device would be what would well be understood in the art as being in the range of microneedles. Furthermore, the Yuzhakov reference is provided as a teaching reference disclosing that it is known to make microneedles the sizes as specified in the claims, and it would have been obvious to modify the size of Barath's or Vigil's device with the teaching of Yuzhakov.

As to Applicant's arguments that the references do not disclose a plate member, Examiner maintains that Applicant has not provided sufficient limitations to overcome the two references. Examiner regards the innermost lining of the catheter balloon (1) of Barath as the plate member, and as such, the microneedles are disposed on the plate and project through the balloon. As to the Vigil reference, the plate (30) forms part of the balloon wall, through which the lumen of the microneedles projects. Newly added claim 34, which is dependent of claim 27 has been objected and would clarify any possible interpretation of the claim and rejection using the current two references.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing

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date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Catherine N Witzak/  
Examiner, Art Unit 3767